

MAR 22 2001

SUMMARY OF SAFETY AND EFFECTIVENESS

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Boston Scientific Corporation is required to submit with this Premarket Notification either an "... adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." Boston Scientific Corporation choose to submit a summary of information respecting safety and effectiveness. According to §513(i)(3)(B), "Any summary under subparagraph (A) respecting a device shall contain detailed information regarding data concerning adverse health effects..."

The summary regarding the adverse health effects of the proposed NIROYAL® Biliary Premounted Stent System is as follows:

Trade Name: NIROYAL® Biliary Premounted Stent System

Manufacturer: Boston Scientific Corporation/ Ireland (BSIL)
Galway, Ireland

Device Generic Name: Biliary Stent

Classification: According to Section 13 of the Federal Food, Drug and Cosmetic Act, the device classification is Class II, Performance Standards.

Predicate Devices: Johnson & Johnson Palmaz® Corinthian IQ Biliary Stent and Delivery System
NIR™ Biliary Stent
Talon Balloon Dilatation Catheter

All of the devices mentioned above have been determined substantially equivalent by FDA.

Device Description:

The proposed NIROYAL® Biliary Premounted Stent System is a balloon expandable stent system. The delivery catheter facilitates transhepatic access to the biliary tree and the stent is designed to maintain luminal patency of biliary strictures produced by malignant neoplasms.

Safety and Performance:

Functional and integrity bench testing and Biocompatibility testing (according to the FDA guidance document, ODE Blue Book Memorandum #G95-1, May 1, 1995, Use of International Standard ISO-10993. "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing") were performed, and the data supported the substantial equivalence of the NIROYAL® Biliary Premounted Stent System to the predicate devices.

Conclusion:

Based on the Indications for Use, technological characteristics and safety and performance testing, the NIROYAL® Biliary Premounted Stent System has been shown to be safe and effective for its intended use.



Food and Drug Administration
4200 Corporate Boulevard
Rockville, MD 20850

MAR 22 2001

Ms. Jodi Lynn Greenizen
Regulatory Affairs Project Manager
Boston Scientific Corporation
One Boston Scientific Place
Natick, Massachusetts 01760

Re: K003929
NIROYAL® Biliary Premounted Stent System
Regulatory Class: II
21 CFR §876.5010
Product Code: 78 FGE
Dated: December 20, 2000
Received: December 20, 2000

Dear Ms. Greenizen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

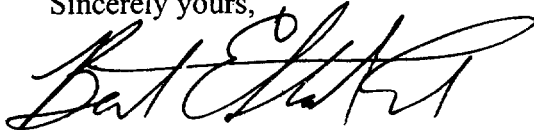
affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. *Please note:* This response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR §807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bernard E. Statland", written over a horizontal line.

Bernard E. Statland, M.D., Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003929

Device Name: Boston Scientific NIRoyal Biliary Premounted Stent System

FDA's Statement of the Indications For Use for device:

The NIRoyal Biliary Premounted Stent System is indicated for use in the treatment of biliary strictures produced by malignant neoplasms. The device is not intended for use in the cardiovascular system.

Prescription Use ☒ OR Over-The-Counter Use ☐
(Per 21 CFR 801.109)



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K003929